ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit)

February 2000

BUDGET ACTIVITY

5 - Engineering and Manufacturing Development

PE NUMBER AND TITLE

0604807A Medical Materiel - Engineering Development

	COST (In Thousands)	FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
	Total Program Element (PE) Cost	5160	9636	6318	8971	13797	11961	12319	Continuing	Continuing
D812	Military Human Immunodeficiency Virus (HIV) Vaccine and Drug- Engineering Development	290	2354	152	1647	5558	3284	3639	Continuing	Continuing
D832	Combat Medical Materiel-Engineering Development	2292	3369	2234	3153	3305	3503	3505	Continuing	Continuing
D834	Soldier System Protection-Engineering Development	895	680	686	883	1547	1830	1828	Continuing	Continuing
D849	Infectious Disease Drug and Vaccine-Engineering Development	1683	3233	3246	3288	3387	3344	3347	Continuing	Continuing

A. <u>Mission Description and Justification</u>: This Engineering and Manufacturing Development Program funds: (1) improved medical equipment and drugs essential to counteracting lethal and human performance degrading effects of infectious diseases and (2) medical equipment essential to meeting medical requirements on the integrated battlefield, with emphasis on decreased size and weight, yet supporting large numbers of combat casualties. Additionally, foreign medical materiel may be procured for exploitation of advanced technology and development to meet Army medical defense goals. This program element supports the full-scale development of vaccines, prophylactic and therapeutic drugs, resuscitation fluids, and drug products for acquired immune deficiency syndrome (AIDS). This program funds engineering and manufacturing development for both large and small combat casualty care end items for location of casualty, diagnosis, rapid intensive care delivery, intensive care evacuation platforms, and rapidly mobile, lightweight surgical facilities and equipment. Additionally, the program element funds engineering and manufacturing development of medical equipment that provides protection against physiological, psychological or environmental factors that degrade physical performance. This program is primarily managed by the U.S. Army Medical Research and Materiel Command.

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Exhibit R-2 (PE 0604807A)

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2 Exhibit) TIVITY PE NUMBER AND TITLE PE NUMBER AND TITLE PATE February 2000

BUDGET ACTIVITY

5 - Engineering and Manufacturing Development

0604807A Medical Materiel - Engineering Development

B. Program Change Summary	FY 1999	<u>FY 2000</u>	<u>FY 2001</u>
Previous President's Budget (<u>FY 2000/2001</u> PB)	5299	9705	9448
Appropriated Value	5338	9705	
Adjustments to Appropriated Value			
a. Congressional General Reductions	-39		
b. SBIR / STTR	-121		
c. Omnibus or Other Above Threshold Adjustments		-38	
d. Below Threshold Reprogramming	+4		
e. Rescissions	-22	-31	
Adjustments to Budget Years Since FY 2000/2001 PB			-3130
Current Budget Submit (FY 2001 PB)	5160	9636	6318

Change Summary Explanation: Funding – FY 2001: Funds realigned from 0604807A, project 812, Military HIV Vaccines and Drug Development to 0603807A, project 811, Military HIV Vaccines and Drug Development.

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Exhibit R-2 (PE 0604807A)

DATE **ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)** February 2000 BUDGET ACTIVITY PE NUMBER AND TITLE **PROJECT** 5 - Engineering and Manufacturing Development 0604807A Medical Materiel - Engineering D812 **Development** FY1999 FY 2000 FY 2001 FY 2002 FY 2003 FY2004 FY2005 Cost to **Total Cost** COST (In Thousands) Actual Estimate Estimate Estimate Estimate Estimate Complete Estimate D812 Military Human Immunodeficiency Virus (HIV) Vaccine and Drug-290 2354 152 1647 5558 3284 3639 Continuing Continuing **Engineering Development**

A. <u>Mission Description and Justification</u>: This project funds Congressionally mandated, militarily relevant human immunodeficiency virus (HIV) medical countermeasures. This provides for engineering and manufacturing development of sufficient candidate vaccines and drugs to permit large-scale field testing and education/training materials. Efforts are directed to answer militarily unique needs affecting manning, mobilization, and deployment. The major contractor is Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD.

FY 1999 Accomplishments:

• 290 Provided regulatory affairs support for New Drug Application submission of GP120 recombinant protein HIV vaccine, required for FDA licensure.

Total 290

FY 2000 Planned Program:

2290 Conduct epidemiological studies to identify locations and cohorts necessary for a large Phase 3 trial for GP120 and GP160.

Small Business Innovative Research/Small Business Technology Transfer Research Programs.

Total 2354

FY 2001 Planned Program:

• 152 Continue epidemiological studies to identify locations and cohorts necessary for a Phase 3 trial for GP120 and GP160.

Total 152

- B. Other Program Funding Summary: Not applicable.
- C. <u>Acquisition Strategy</u>: Test and evaluate commercially developed vaccine candidates in government-managed trials.
- D. Schedule Profile: Not applicable.

Project D812 Page 3 of 13 Pages Exhibit R-2A (PE 0604807A)

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)									February 2000		
BUDGET ACTIVITY 5 - Engineering and Manufacturing Developm	ent		PE NUMBER AND 0604807A Developme	Medical N	/lateriel -	Enginee	ring		PROJECT D832		
COST (In Thousands)	FY1999 Actual	FY 200 Estimat		FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost		
D832 Combat Medical Materiel-Engineering Development	2292	3	3369 2234	3153	3305	3503	3505	Continuing	Continuing		

A. <u>Mission Description and Justification</u>: The project supports engineering and manufacturing development to field new and improved medical materiel essential for combat casualty care to reduce the logistical support requirements and minimize loss. The major contract is United Defense Limited Partnership, San Jose, CA.

FY 1999 Accomplishments:

- 90 Completed initial prototype and development of Special Operations Resuscitation and Surgical Suite.
- 248 Conducted transportability evaluation of Critical Care System for Trauma and Transport (CSTAT).
- 1885 Conducted a Milestone (MS) I/II for Armored Medical Evacuation Vehicle (AMEV). Incorporated test recommendation from National Training Center rotation in redesign of AMEV for engineering and manufacturing development (EMD) vehicle.
- 33 Completed final evaluation of Patient Movement Item (litter/gurney for Special Forces).
- 36 Initiated sample analysis of clinical data related to Hypertonic Saline Dextran.

Total 2292

FY 2000 Planned Program:

- 498 Conduct technology cost-benefit trade-off analysis and initiate formal acquisition program for CSTAT device.
- 1696 Receive delivery of AMEV EMD vehicle and conduct limited user test.
- 1015 Conduct an MS I In-Process Review (IPR) for Hemostatic Dressing, select best products to move into Food and Drug Administration (FDA) approval process and initiate Phase 1 safety trials.
- Complete in vitro and in vivo studies for FDA submittal of the Thawed Blood Processing System (TBPS). Conduct MS I/II
- Small Business Innovative Research/Small Business Technology Transfer Research Programs.

Total 3369

FY 2001 Planned Program:

- 843 Complete safety trials of Hemostatic Dressing, hold a MS II In-Process Review (IPR), and initiate efficacy trials in human elective surgery clinical trials.
- 121 Conduct clinical trials on Next Generation Jet Injector.
- 51 Prepare initial operational test and evaluation for Warrior Medic program and conduct a MS II/III IPR.
- 1021 Conduct product qualification test, logistics demonstration and low rate initial production IPR for AMEV.

Project D832 Page 4 of 13 Pages Exhibit R-2A (PE 0604807A)

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)

DATE February 2000

BUDGET ACTIVITY

5 - Engineering and Manufacturing Development

PE NUMBER AND TITLE

0604807A Medical Materiel - Engineering

PROJECT **D832**

Development

FY 2001 Planned Program: (continued)

- 123 Submit and attain FDA approval of the TBPS.
- 75 Conduct an MS III for the CSTAT.

Total 2234

- B. Other Program Funding Summary: Not applicable.
- C. Acquisition Strategy: Evaluate commercially developed materiel in government-managed trials.

D. Calcadula Duagila	EV 1006	EV 1007	EV 1000	EV 1000	EV 2000	EV 2001	EX 2002	EV 2002	EV 2004	EV 2005
D. Schedule Profile	FY 1996	<u>FY 1997</u>	<u>FY 1998</u>	<u>FY 1999</u>	FY 2000	FY 2001	<u>FY 2002</u>	FY 2003	FY 2004	FY 2005
AMEV				MS I/II					MS III	
				3QTR					3QTR	
CSTAT						MS III				
						4QTR				
Warrior Medic						MS II/III				
						4QTR				
Hemostatic Dressing					MS I	MS II			MS III	
					4QTR	4QTR			4QTR	
Next Generation Jet Injector							MS II/III			
							3QTR			
TBPS					MS I/II		MS III			
					3QTR		1QTR			
Medium Armored Vehicle - Medical									MS II	
									1QTR	
10-week Blood								MS III		
								2QTR		
Hemostatic Foam									MS II	
									4QTR	

Project D832 Page 5 of 13 Pages Exhibit R-2A (PE 0604807A)

DATE **ARMY RDT&E COST ANALYSIS (R-3)** February 2000 BUDGET ACTIVITY PE NUMBER AND TITLE **PROJECT** 5 - Engineering and Manufacturing Development 0604807A Medical Materiel - Engineering D832 **Development** I. Product Development Contract Performing Activity & Total FY 1999 FY 1999 FY 2000 FY 2000 FY 2001 FY 2001 Cost To Total Target PYs Cost Method & Location Cost Award Cost Award Cost Award Complete Cost Value of Type Contract Date Date Date PM Bradley, Warren Nov 99 AMEV **MIPR** 1938 1929 Nov 98 3369 Nov 00 9002 1766 Continue ΜI Subtotal Product 1938 1929 1766 9002 3369 Development: II. Support Costs: No product/contract costs greater than \$1M individually III. Test and Evaluation: No product/contract costs greater than \$1M individually FY 1999 FY 2001 IV. Management Services Contract Performing Activity & Total FY 1999 FY 2000 FY 2000 FY 2001 Cost To Total Target Award Method & Location PYs Cost Cost Award Cost Award Cost Complete Cost Value of Type Date Date Date Contract a. No product/contract costs 260 363 468 1091 Continue greater than \$1M individually Subtotal Management 260 363 468 1091 Services: Project Total Cost: 2234 2198 2292 3369 10093

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Exhibit R-3 (PE 0604807A)

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Project D832

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)									February 2000		
BUDGET ACTIVITY 5 - Engineering and Manufacturing Developm	nent	0	6048	BER AND B 807A N Blopmei	Medical M	lateriel -	Enginee	ring		PROJECT D834	
COST (In Thousands)	FY1999 Actual	FY 2000 Estimate		FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost	
D834 Soldier System Protection-Engineering Development	895	6	80	686	883	1547	1830	1828	Continuing	Continuin	

A. <u>Mission Description and Justification</u>: This project supports engineering development of preventive medicine materiel, including devices, pharmacologicals, and other tools to provide protection, sustainment, and enhancement of the physiological and psychological capabilities of soldiers in the face of combat operations under all environmental conditions. Focus is on reduction in the incidence of personnel losses due to preventable disease and nonbattle injuries through development of environmental and physiological performance monitors and other preventive medicine countermeasures.</u> A major contractor is Stanford Research Institute, Palo Alto, CA.

FY 1999 Accomplishments:

- Provided system engineering support for system integration with the Force XXI Battle Command Brigade and Below (FBCB2) and Ground Combat Support System. Conduct MS III.
- Provided hardware infrastructure support for Theater Medical Information Program (TMIP) block 1 initial operational test and evaluation (IOT&E). Conduct MS III.

Total 895

FY 2000 Planned Program:

- 201 Provide engineering contract support for TMIP-A block 2 IOT&E. Conduct MS III
- 461 Provide manufacture support of *Leishmania* skin test antigen (LSTA) kits for Phase 2 clinical trials.
- Small Business Innovative Research/Small Business Technology Transfer Research Programs.

Total 680

FY 2001 Planned Program:

- 200 Provide engineering contract support for TMIP-A block 3 IOT&E. Conduct MS III.
- 486 Provide manufacture support of *Leishmania* skin test antigen (LSTA) kits for Phase 2 clinical trials.

Total 686

- B. Other Program Funding Summary: Not applicable.
- C. <u>Acquisition Strategy</u>: Test and evaluate in-house and commercially developed vaccine candidates in government-managed trials to meet FDA requirements.

Project D834 Page 7 of 13 Pages Exhibit R-2A (PE 0604807A)

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A Exhibit)							DATE February 2000				
BUDGET ACTIVITY 5 - Engineering and Manufacturing	ng Developme	ent	0604	MBER AND TI 4807A M elopmen	edical Ma	Engineer	ring PROJECT				
D. Schedule Profile	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 200	
TMIP block 1				MS III 3QTR							
TMIP block 1 infrastructure support				MS III 3QTR							
TMIP block 2					MS III 3QTR						
TMIP block 2 infrastructure support					MS III 3QTR						
TMIP block 3						MS III 3QTR		_	_		
TMIP block 3 infrastructure support						MS III 3QTR					
LSTA									MS III 4QTR		
Project D834			Page 8 of 1.	3 Pages			Exhibit	R-2A (PE ()604807A)		

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ARMY RDT&E BUDGET ITE	M JUS	TIFICA	TION (R-	2A Exh	ibit)		DATE Fe	bruary 2	000
5 - Engineering and Manufacturing Developm	06	PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development						PROJECT D849	
COST (In Thousands)	FY1999 Actual	FY 2000 Estimate	FY 2001 Estimate	FY 2002 Estimate	FY 2003 Estimate	FY2004 Estimate	FY2005 Estimate	Cost to Complete	Total Cost
D849 Infectious Disease Drug and Vaccine-Engineering Development	1683	323	3 3246	3288	3387	3344	3347	Continuing	Continuing

A. <u>Mission Description and Justification</u>: This project funds engineering and manufacturing development of sufficient candidate medical countermeasures to permit large-scale field testing and complete studies required for Food and Drug Administration (FDA) licensure. Work performed in laboratories and among troop populations is directed to prevention, diagnosis, and treatment of viral, bacterial, and parasitic diseases to prevent casualties, sustain operational performance, and minimize deaths and disability of armed forces during military operations.

FY 1999 Accomplishments:

- 672 Initiated Phase 3 study in Egyptian infants and children of enterotoxigenic *Escherichia coli* (ETEC) vaccine.
- 319 Initiated Phase 3 pivotal trial in Israel of ETEC vaccine.
- 640 Completed Phase 2 clinical rechallenge study for adjuvant Campylobacter vaccine.
- 52 Obtained agreement of two separate European manufacturers to investigate FDA licensing for tickborne encephalitis (TBE) vaccine.

Total 1683

FY 2000 Planned Program:

- 103 Conduct Phase 2 efficacy study for improved dose regiment of adjuvanted Campylobacter vaccine.
- 188 Conduct Phase 1 safety trials of new adjuvant lot of Campylobacter vaccine.
- 191 Initiate Phase 2 efficacy study for new adjuvant lot of Campylobacter vaccine.
- 1180 Initiate three Phase 3 long-term prophylaxis clinical drug trials on Tafenoquine, an antimalarial drug.
- 83 Complete and analyze Indonesia trial on Primaquine, an antimalarial drug.
- 50 Conduct a Milestone (MS) 0/II In-Process Review (IPR) on Primaquine.
- 90 Prepare an Investigational New Drug application (IND) on Primaquine.
- 50 Conduct a MS I/II IPR on Malarone; complete Phase 3 clinical trial in Indonesia.
- 457 Continue Phase 3 study in Egyptian infants and children with ETEC vaccine.
- 203 Continue 2-year rat carcinogenicity study of Tafenoquine (initiated in FY 1999, see Project D808).
- 181 Prepare IND application for TBE vaccine.
- 386 Continue Phase 3 trial in Israel of ETEC vaccine.

Project D849 Page 9 of 13 Pages Exhibit R-2A (PE 0604807A)

		ARMY RDT&E BUDO	SET ITE	M JUST	IFICATI	ON (R-2	2A Exhib	oit)		DATE Fel	oruary 20	00
BUDGET A 5 - Eng		g and Manufacturing De	evelopme	ent	0604	MBER AND T 4807A M elopmen	edical M	ateriel - E	Engineer		PI	ROJECT 0849
FY 2000	Planned 1	Program: (continued)										
•	71	Small Business Innovative Res	search/Small	Business To	echnology Tr	ransfer Rese	arch Progra	ms.				
Total	3233						_					
FY 2001	Planned P	rogram:										
•	133	Complete Phase 3 study in Egy	yptian infant	s and childre	en.							
•	499	Complete Phase 3 pivotal trial	in Israel of l	ETEC vacci	ne.							
•	174	Complete expanded Phase 2 ef				1.0						
•	204	Plan and initiate Phase 3 pivot				•	ccine.					
•	1056	Continue six clinical drug trial		•		ug.						
•	51	Submit New Drug Application		on Primaqu	ine.							
•	50	Conduct a MS III IPR on Prim										
•	179	Prepare Biologics License App		TBE vaccine	and submit	to the FDA.						
•	50	Conduct a MS III IPR on TBE										
•	200	Prepare Pre-Market Application		-	_	ice.						
•	50	Conduct a MS II IPR for Mala		_								
•	600	Complete 2-year rat carcinoge	nicity study of	of Tafenoqui	ine.							
Total	3246											
B. Other	Program	Funding Summary: Not applic	able.									
C. Acquis	sition Stra	tegy: Test and evaluate in-hous	se and comm	ercially deve	eloped vaccii	ne candidate	es in governi	nent-manag	ed trials to r	neet FDA re	equirements.	
D. Sche	dule Profi	le	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 2005
	nia skin tes										MS III	
											4QTR	
Camoufla	age face pa	int								MS III		
										4QTR		
Tafenoqu	iine antima	alarial								MS III		<u> </u>
										2QTR		

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Exhibit R-2A (PE 0604807A)

Project D849

ARMY RDT&E BUDGET ITEM JUSTIFICATION (R-2A EXHIBIT)								DATE February 2000			
BUDGET ACTIVITY 5 - Engineering and Manufactur	ing Developme	ent	060	JMBER AND T 4807A M Velopmen	ledical M	PROJECT D849					
D. Schedule Profile	FY 1996	FY 1997	FY 1998	FY 1999	FY 2000	FY 2001	FY 2002	FY 2003	FY 2004	FY 200	
Dengue rapid diagnostic device								MS II/III 4QTR			
ETEC vaccine								MS III 2QTR			
Malaria Rapid Diagnostic Device								MS III 2QTR			
Primaquine antimalarial					MS II 2QTR	MS III 4Q0TR		24			
Malarone antimalarial					MS II 2QTR	. Quitt	MS III 4QTR				
TBE vaccine					2411	MS III 4QTR					
Scrub typhus diagnostic device						- iQIII	MS II 4QTR	MS III 2QTR			
Project D849		1	Page 11 of	13 Pages			Exhibit	R-2A (PE 0	0604807 <u>A)</u>		

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	Al	RMY RDT&E CO	OST AN	IALYS	IS (R-3))			DA		uary 200	00	
BUDGET ACTIVITY 5 - Engineering and	BUDGET ACTIVITY 5 - Engineering and Manufacturing Development							PE NUMBER AND TITLE 0604807A Medical Materiel - Engineering Development					
I. Product Development	Contract Method & Type	Performing Activity & Location	Total Pys Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a. No product/contract costs greater than \$1M individually			43								43		
Subtotal Product Development			43								43		
II. Support Costs	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a. No product/contract costs greater than \$1M individually	J.F.		29	58		98		98		Continue	283		
Subtotal Support Costs:			29	58		98		98			283		
III. Test and Evaluation	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of Contract	
a. No product/contract costs greater than \$1M individually	J.F.		677	1036		2010		2048		Continue	5771		
Subtotal Test and Evaluation:			677	1036		2010		2048			5771		
IV. Management Services	Contract Method & Type	Performing Activity & Location	Total PYs Cost	FY 1999 Cost	FY 1999 Award Date	FY 2000 Cost	FY 2000 Award Date	FY 2001 Cost	FY 2001 Award Date	Cost To Complete	Total Cost	Target Value of	
a. No product/contract costs greater than \$1M individually			380	589		1138		1142		Continue	3249		
Project D849				Page 12 o	f 13 Pages				Exhibit R	-3 (PE 060	4807A)		

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	ARMY RDT&E COST AN	IALYSIS (I	R-3)		February 2000
JDGET ACTIVITY - Engineering and Manuf	acturing Development		R AND TITLE 17A Medical Ma pment	PROJECT PROJEC	
Subtotal Management Services:	380	589	1138	1142	3249
	Total PYs Cost	FY 1999 Cost	FY 2000 Cost	FY 2001 Cost	Total Cost
Project Total Cost:	1129	1683	3246	3288	9346

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